



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/524,334

02/11/2005

Benjamin Oshlack

200.1156US

6951

23280 7590 01/07/2009
Davidson, Davidson & Kappel, LLC
485 7th Avenue
14th Floor
New York, NY 10018

EXAMINER

AHMED, HASAN SYED

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

01/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Receipt is acknowledged of applicants' amendment/response (filed on 22 September 2008) and IDS (filed on 15 December 2008).

* * * * *

Claim Objections

Claim 19 objected to because of the following informalities: claims 18-52 have been cancelled. Thus the new claim should be claim 53. Appropriate correction is required.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 10-17 remain rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,955,104 ("Momberger").

Momberger discloses a pharmaceutical formulation comprising:

- the opioid antagonist (naloxone) of instant claim 1 (see col. 3, line 12);
- the diffusion barrier coating comprising an anionic polymer of instant claim 1 (see col. 2, lines 42-65; col. 4, line 39);
- the coating comprising a hydrophobic material of instant claim 1 (see col. 2, lines 42-65; col. 4, lines 56-59);

Art Unit: 1615

- the opioid antagonist coated over a core of instant claim 2 (see col. 2, lines 42-65; col. 3, line 12);
- the inert bead (core) of instant claim 3 (see col. 2, line 45);
- the dispersed antagonist of instant claim 4 (see col. 3, lines 65-68);
- the methacrylic polymer of instant claim 7 (see col. 4, line 39);
- the diffusion barrier coating (binder) amount of instant claim 10 (see col. 2, line 55);
- the plurality of substrates (pellets) of instant claim 12 (see col. 2, line 43);
- the cellulosic polymer of instant claim 16 (see col. 4, line 57); and
- the naloxone of instant claim 17 (see col. 3, line 12).

The properties recited in instant claims 5, 6, 11, and 13-15 are inherent properties of the claimed composition.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,955,104 ("Momberger").

Momberger discloses a pharmaceutical formulation (see above). Momberger differs from the instant application in that it does not disclose the particular species of opioid antagonist disclosed in instant claim 19. However, Momberger discloses use of a different opioid antagonist, i.e. naloxone (see col. 3, line 12). Because both naloxone and naltrexone are opioid antagonists, a person of ordinary skill in the art would have been motivated to add either naloxone or naltrexone to the instant formulation. There is a reasonable expectation that the addition of either naloxone or naltrexone to the instant formulation would provide effective opioid antagonism. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add either naloxone or naltrexone to the instant claimed formulation.

* * * * *

Response to Arguments

Applicants arguments filed on 22 September 2008 have been fully considered but they are not persuasive.

1. Applicants argue that, “Momberger states that in the formulation described therein ‘the binder solution does **not coat** or embed the active ingredient particles.’...”
See remarks, page 6.

Examiner respectfully submits that Momberger anticipates the instant application as claimed.

Instant claim 1 does not require that active ingredient particles be coated. Rather, the anionic polymer is to coat the substrate. Furthermore, claim 1 does not require that the substrate be completely coated.

Momberger discloses the same amount of anionic polymer as is claimed in instant claim 10 (*i.e.* up to 10%). Furthermore, Momberger discloses spraying of the polymer (binder) on the active (*i.e.* at least partial coating) (see col. 3, lines 39-40). Thus, giving the term “coating” its broadest reasonable interpretation, examiner respectfully submits that Momberger anticipates the instant application, as claimed.

2. Applicants argue that the limitation of instant claim 4 is not met because Momberger states that the active ingredient is not embedded in any embedding material or matrix. See remarks, page 6.

Again, examiner respectfully submits that the instant application is anticipated by Momberger as claimed.

Instant claim 4 recites dispersion of agent in matrix multiparticulates. While Momberger does not disclose embedding of an agent in a matrix material, Momberger does not forbid dispersion. In fact, Momberger explicitly discloses dispersion (*i.e.* admixture) of agent with additional materials, such as colloidal silica (see col. 3, line 66).

3. Applicants argue that arguments rejecting claims under the theory of inherency (claims 5, 6, 11, and 13-15) are not properly supported. See remarks, page 7.

Instant claim 5 recites an opioid antagonist that is protonated. Naloxone (disclosed by Momberger) is protonated. Instant claim 6 recites a protonated opioid antagonist with affinity for anionic polymer. Since a protonated opioid will be positively charged, it will inherently have affinity for an anionic polymer, which is negatively charged. Instant claims 11 and 13 recite antagonist in a therapeutically effective amount. All pharmaceutical formulations contain therapeutic agents in a therapeutically

effective amount, otherwise the formulation will have no purpose. As for claims 14 and 15, controlled release and sequestration are inherent properties of hydrophobic materials.

* * * * *

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

This application contains claims 8 and 9 drawn to an invention nonelected with traverse in the reply filed on 14 April 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

Application/Control Number: 10/524,334
Art Unit: 1615

Page 8